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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 10/538,913
Filing Date: September 29, 2005
Appellant(s): VENTURELLI, ANDREA

Charles W. Fallow
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed September 14th 2009 appealing from the Office action mailed November 17th 2008.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

US 5,935,162	DANG	8-1999
US 6,540,775	FISCHELL et al.	4-2003
US 2002/0183763	CALLOL et al.	12-2002
US 2002/0065547	MOORE	5-2002
US 6,299,604	RAGHEB et al.	10-2001

(9) Grounds of Rejection

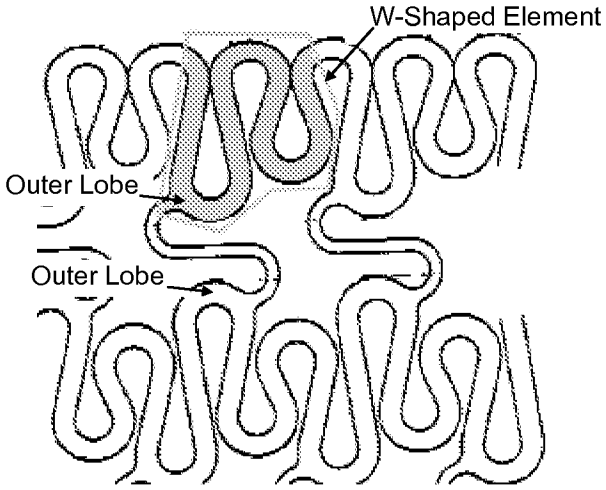
The following ground(s) of rejection are applicable to the appealed claims:

Claims 1-17, 19-21, 23-31, 34, 40, 41, 43-46, and 51-53 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dang (US 5,935,162) in view of Fischell et al. (US 6,540,775).

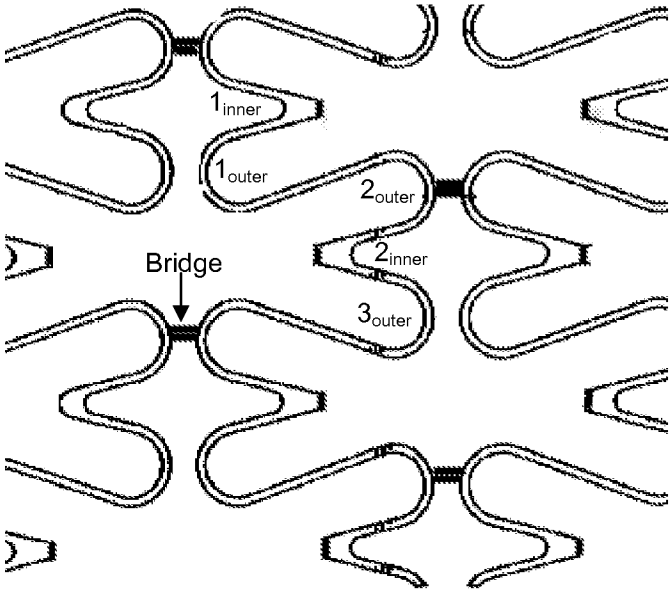
Dang discloses an expandable endolumenal prosthesis comprising in the non-expanded configuration: a tubular body (Fig. 1), the tubular body having a porous wall defined by a plurality of interlaced circumferential lines forming a pathway motif or pattern (Fig. 2) in which at least one line is closed onto itself (Fig. 2; col. 4, lines 41-43), each of the lines extends along an axis (implicit for cylindrical sections as in col. 4, lines 41-43), each of the lines comprises at least one plurality of modules 30 (Fig. 2; col. 4,

lines 57-59), each module comprises three lobes, that is, two outer lobes and one inner lobe (in addition to module 30, inner and outer lobes can be defined arbitrarily in the prior art; consider the lower left of Fig. 2, going from down to up, three bends define three lobes: the bend to the left adjacent to the bridge defines an outer lobe, the following bend to the right defines an inner lobe and the following bend defines an outer lobe) disposed between the two outer lobes in the pathway of the pattern, each lobe comprising one or more curved sections having concavities facing in the same direction, defining an apex of the lobe (Fig. 2; any curved portion of the lobe defines a concavity; the interior corners of the lobe apex define the concavities as claimed), the lobes opening alternately on opposite sides of the pathway of the pattern along the extent of the line (col. 5, lines 29-31), both of the outer lobes of the three lobes being extended by straight outer arms (evident from Fig. 2), the at least one plurality of modules being arranged consecutively so as to have successive outer arms which extend from the outer lobes in substantially opposite directions relative to the pathway of the pattern for two successive modules (evident from Fig. 2 for the above described modules; this limitation can be met by the outer arms of a single module, however the outer arms of adjacent modules 30 also meet this limitation), for each module, the distance between the apex of one of the outer lobes and the apex of the inner lobe of the same module is less than the distance between the apex of the same outer lobe and the apex of any outer lobe of an adjoining module (less than the distance as claimed for adjoining modules within the same circumferential line; Fig. 2), for each line, there is at least one adjacent line which has a motif that is a mirror image of the said line with respect to an

axis parallel to the axis of the line (evident from Fig. 2), at least one connecting element or bridge is provided between two adjacent lines (Fig. 3, item 50), and in which said bridge connects two faced outer lobes of two adjacent lines, said bridge extends along a longitudinal axis parallel to the longitudinal axis of the tubular body (Fig. 2). Dang does not disclose the bridges directly connect opposed outer lobes of adjacent lines wherein each bridge is provided between two adjacent lines, for every five complete lobes of a line, three outer lobes and two inner lobes. Fischell et al. teach using bridges to attach one outer lobe of opposing w-shaped modules for increased flexibility while allowing for the stent to have a reduced diameter upon crimping onto a balloon, as well as reduced flaring of the outer lobes (col. 2, lines 37-50; col. 2, lines 58-63; col. 3, lines 17-23; col. 3, lines 31-36; col. 5, lines 10-14; col. 5, lines 2-9 – here, in addition to providing one shortened outer lobe, Fischell et al. essentially teach that providing bridges on every other outer lobe prevents the bridges from interfering with eachother when the stent is crimped to a small diameter). See below:



Therefore, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify Dang's stent to include Fischell et al.'s bridges. Such a modification allows for improved flexibility, minimum crimpable diameter and reduced outer lobe flaring. Furthermore, since Dang discloses that the bridge (tie members) should connect modules ("w-shaped" elements) that open up towards eachother (Abstract; Figure 2), it would have been obvious to one of ordinary skill in the art to attach outer lobes (in view of Fischell et al.) only to modules that open up towards eachother (in view of Dang). This would result in the structure shown below (of course with Fischell et al.'s extended bridge shape) which meets the limitations of Appellant's claim 1.



Regarding claim 2, Dang discloses the inner lobe of at least one module being extended by at least one straight inner arm (evident from Fig. 2). Regarding claim 3, Dang discloses both of the ends of the inner lobe being extended by straight arms (evident from Fig. 2). Regarding claim 4, Dang discloses at least one of the outer arms extends along an axis which is inclined to the longitudinal axis of the tubular body and is also inclined to the axis of the line to which the module belongs (evident from Fig. 2). Regarding claim 5, Dang discloses both of the outer arms of the module extend along respective axes which are inclined to the longitudinal axis of the tubular body and are also inclined to the axis of the line to which the module belongs (evident from Fig. 2). Regarding claim 6, Dang discloses the outer arms of the module extend away from the lobes along converging axes (evident from Fig. 2). Regarding claim 7, Dang discloses the arms have inclinations substantially close to the direction of the longitudinal axis of the prosthesis when the prosthesis is in the non-expanded configuration (evident from Fig. 2). Regarding claim 8, Dang discloses the inclination of the arms is selected in a manner such that, when the prosthesis is in the expanded configuration, the arms are arranged substantially close to the direction transverse the longitudinal axis of the prosthesis (evident from Fig. 2). Regarding claim 9, Dang discloses at least one outer arm of a module is shared with the adjacent module (evident from Fig. 2). Regarding claim 10, Dang discloses all of the outer arms of each module are shared with adjacent modules (evident from Fig. 2). Regarding claim 11, Dang discloses the outer arms are of equal extent (evident from Fig. 2). Regarding claim 12, Dang discloses the inner lobe being extended by two straight inner arms (evident from Fig. 2). Regarding claim 13,

Dang discloses the inner arms are of equal extent (evident from Fig. 2). Regarding claim 14, Dang discloses the inner lobe is joined to the outer lobes by means of at least one inner arm (evident from Fig. 2). Regarding claim 15, Dang discloses the inner lobe and the inner arm or arms have an overall extent less than the overall extent of the outer lobes and the respective outer arms (evident from Fig. 2). Regarding claim 20, Dang discloses at least one module has two inner arms of equal extent (evident from Fig. 2). Regarding claim 23, Dang discloses at least one module comprises at least one lobe comprising at least one curved section of predefined extent suitable for determining the aperture of the cell which faces it (Fig. 2; any curved section of any lobe in Dang can be regarded in this manner). Regarding claim 24, Dang discloses at least one module comprises at least one lobe comprising at least one curved section of predefined extent suitable for arranging the arms substantially parallel to the longitudinal axis of the prosthesis when it is in the non-expanded or clenched configuration (evident from Fig. 2). Regarding claim 25, Dang discloses at least one module comprises at least one lobe comprising at least one curved section of predefined extent suitable for arranging the arms substantially transverse the longitudinal axis of the prosthesis when it is in the expanded configuration (evident from Fig. 2). Regarding claim 26, Dang discloses at least one module comprises at least one lobe comprising a plurality of curved sections with concavities having the same orientation (evident from Fig. 2; see above comments for claim 1). Regarding claim 27, Dang discloses at least one module comprises at least one lobe comprising a plurality of curved sections with concavities having the same orientation and at least one interposed straight section (Fig 2; a

straight section of an outer arm crosses over the direction which two concavities or portions of the adjoining lobe face). Regarding claim 28, Dang discloses the inner lobe is joined directly to one of the outer lobes (evident from Fig. 2). Regarding claim 29, Dang discloses all of the modules of a line have identical characteristics (evident from Fig. 2). Regarding claim 31, Dang discloses in at least one line, the same module is repeated along the pathway of the line in a mirror-image arrangement with respect to an axis parallel to the axis of the line (evident from Fig. 2). Regarding claim 40, Dang discloses at least one module is substantially M-shaped and is arranged so as to have outer arms directed substantially either towards the distal end or towards the proximal end (evident from Fig. 2). Regarding claim 41, Dang discloses the axis of the line is substantially perpendicular to the longitudinal axis of the tubular body (evident from Fig. 2). Regarding claim 43, Dang discloses the line axis is straight or circumferential (evident from Fig. 2). Regarding claim 44, Dang discloses for each line, there is at least one adjacent line which has a motif that is a mirror image of the said line with respect to an axis parallel to the axis of the line (evident from Fig. 2). Regarding claim 45, Dang discloses at least one connecting element or bridge is provided between two adjacent lines (Fig. 3 Item 50; or as modified by Fischell et al. and described above). Regarding claim 46, Dang discloses the bridge defines the interlacing of the lines (evident from Fig. 2). Regarding claim 51, Dang discloses along the line, a bridge is provided between two adjacent lines, for every first or second outer lobe having the same orientation (Fig. 3 Item 50; or as modified by Fischell et al. and described above). Regarding claim 52, Dang discloses a bridge is provided for every module of the line (evident from Fig. 2).

Regarding claim 53, Dang discloses between two adjacent lines, a continuous closed pathway is provided, disposed between two bridges defining a cell (evident from Fig. 2).

Regarding claims 16, 17, 19, 21, 30, and 34, Dang does not disclose the outer and inner lobes with their outer arms and inner arms, respectively, have a non-uniform extent in a direction transverse the axis of the line; the outer or inner arms have an extent which varies in the modules of the same line; the outer arms of the same module have different extents; at least one module has two inner arms of different extents; in at least one line, two pluralities of modules are provided, alternating with one another so as to provide a series of a module of a first plurality and a module of the second plurality; at least one module has outer lobes that are disposed at different distances from the axis of the line. Fischell et al. teach that the outer and inner lobes with their outer arms and inner arms, respectively, have a non-uniform extent in a direction transverse the axis of the line (Fig 1 L3); the outer or inner arms have an extent which varies in the modules of the same line (Fig 1 19L and 19M); the outer arms of the same module have different extents (Fig 1 19L and 19M); at least one module has two inner arms of different extents (Fig 1 19S and 19L); in at least one line, two pluralities of modules are provided, alternating with one another so as to provide a series of a module of a first plurality and a module of the second plurality (Fig. 1, as one example: one module begins with Item 24MC and ends at Item 24MU, the next module begins immediately following Item 24MU and encompasses three lobes; again modules can be drawn arbitrarily and similarly, two pluralities can be drawn from the modified Dang stent shown above); at least one module has outer lobes that are disposed at different

distances from the axis of the line (Fig 1 L3). Regarding claim 16, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify Dang's stent to include Fischell et al.'s non-uniform extent. Such a modification would reduce the tendency of flaring outward when the stent is advanced through a curved vessel (col. 5, lines 17-31 of Fischell et al.). Regarding claim 17, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify Dang's stent to include Fischell et al.'s varied extent. Such a modification would reduce the tendency of flaring outward when the stent is advanced through a curved vessel (col. 5, lines 17-31 of Fischell et al.). Regarding claim 19, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify Dang's stent to include Fischell et al.'s outer arms. Such a modification would reduce the tendency of flaring outward when the stent is advanced through a curved vessel (col. 5, lines 17-31 of Fischell et al.). Regarding claim 21, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify Dang's stent to include Fischell et al.'s inner arms. Such a modification would reduce the tendency of flaring outward when the stent is advanced through a curved vessel (col. 5, lines 17-31 of Fischell et al.). Regarding claim 30, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify Dang's stent to include Fischell et al.'s two pluralities of modules. Such a modification would reduce the tendency of flaring outward when the stent is advanced through a curved vessel. Regarding claim 34, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to

modify Dang's stent to include Fischell et al.'s outer lobes. Such a modification would reduce the tendency of flaring outward when the stent is advanced through a curved vessel.

Claims 18, 22, 32, 33, 35-39, 47-49, and 54 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dang (US 5,935,162) in view of Fischell et al. (US 6,540,775) as applied to claim 1, and further in view of Callol et al. (US 2002/0183763).

Dang and Fischell et al. disclose the invention substantially as claimed as stated above. They do not disclose the outer or inner arms have an extent which varies in the modules disposed along the longitudinal axis of the tubular body of the prosthesis; at least one module having a single inner arm; in at least one line, the pathway is interrupted so as to form an opening in the pattern suitable for the passage of an SDS guide wire; the pathway is interrupted to an extent equal to one module; the pathway is interrupted to an extent equal to five lobes; the pathway is interrupted between two connecting bridges between the line and adjoining lines; the pathway is interrupted in two adjacent lines; the bridge comprises a bridge lobe; the bridge comprises two bridge lobes; the bridge comprises three bridge lobes. Callol et al. teach that the outer or inner arms have an extent which varies in the modules disposed along the longitudinal axis of the tubular body of the prosthesis (Fig. 7A Items 26, 28, and 29); at least one module has a single inner arm (Fig 8 Item 28); the prosthesis comprises lines comprising several pluralities of modules (Fig 7A Item 28 and top line of Item 29); the prosthesis

comprises three pluralities of modules (Fig. 7B Item 45, Item 34, and the module directly above Item 34); in at least one line, the pathway is interrupted so as to form an opening in the pattern (Fig. 8 Item 40); the pathway is interrupted to an extent equal to one module (Fig. 8 Item 40); the pathway is interrupted to an extent equal to five lobes (Fig. 8 Item 40); the pathway is interrupted between two connecting bridges between the line and adjoining lines (Fig. 8 Item 40); the pathway is interrupted in two adjacent lines (Fig 8 Item 40); the bridge comprises a bridge lobe (Fig. 21 Item 33); the bridge comprises two bridge lobes (Fig. 21 Item 33); the bridge comprises three bridge lobes (Fig. 21 Item 33); a variation of the cell perimeter is provided along the longitudinal axis of the prosthesis (Fig 7A Item 28). Regarding claim 18, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify Dang's stent to include Callol et al.'s varied extent. Such a modification would allow the stent to be placed in a bifurcated vessel and cover the main vessel and a portion of the side branch vessel. Regarding claim 22, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify Dang's stent to include Callol et al.'s single inner arm. Such a modification would allow for the passage of a balloon. Regarding claim 32, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify Dang's stent to include Callol et al.'s pluralities of modules. Such a modification would allow the stent to be placed in a bifurcated vessel and cover the main vessel and a portion of the side branch vessel. Regarding claim 33, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify Dang's stent to

include Callol et al.'s three pluralities of modules. Such a modification would allow the stent to be placed in a bifurcated vessel and cover the main vessel and a portion of the side branch vessel. Regarding claims 35-39, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify Dang's stent to include Callol et al.'s interruption. Such a modification would allow for the passage of a balloon. Regarding claims 47-49, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify Dang's stent to include Callol et al.'s bridge lobes. Such a modification would enhance the flexibility of the stent. Regarding claim 54, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify Dang's stent to include Callol et al.'s variation of cell perimeter. Such a modification would allow the stent to be placed in a bifurcated vessel and cover the main vessel and a portion of the side branch vessel.

Claim 42 is rejected under 35 U.S.C. 103(a) as being unpatentable over Dang (US 5,935,162) in view of Fischell et al. (US 6,540,775) as applied to claims 1 and 41, and further in view of Moore (US 2002/0065547).

Dang and Fischell et al. disclose the invention substantially as claimed as stated above. They do not disclose the line axis is inclined to the longitudinal axis at an angle of between 5 degrees and 45 degrees and preferably between 10 and 30 degrees. Moore teaches the line axis is inclined to the longitudinal axis at an angle of between 5 degrees and 45 degrees and preferably between 10 and 30 degrees (Fig 1 a line

forming a pathway motif can be defined by the two points 40 and 15. Its inclination is about 30 degrees). Therefore, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify Dang's stent to include Moore's angle. Such a modification would give the stent superior flexibility characteristics.

Claims 55 and 56 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dang (US 5,935,162) in view of Fischell et al. (US 6,540,775) as applied to claim 1, and further in view of Ragheb et al. (US 6,299,604).

Dang discloses the invention substantially as claimed as stated above. Dang does not disclose the prosthesis comprises an external or internal coating; the coating comprises a drug. Ragheb et al. teach the prosthesis comprising an external coating (col 3, lines 6-18) and the coating comprising a drug (col 3, lines 6-18). Therefore, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify Dang's stent to include Ragheb et al.'s drug coating. Such a modification would allow a drug to be applied at the site of injury.

(10) Response to Argument

Appellant has argued on page 4 of the appeal brief that Dang does not disclose the limitations identified by letters e, g, i, j, m and n in the Summary of Claimed Subject Matter. Examiner respectfully disagrees. It has been described in detail above how those limitations are met by Dang. Examiner has only proposed modifying Dang in view

of Fischell et al. to meet the limitations desginated by letter “o”. Appellant has argued on page 4 of the appeal brief that neither Dang nor Fischell et al. suggest or teach the modifications proposed above. Dang suggests that the length of the bridges can be modified in order to create a suitable combination of torsional stability and longitudinal flexibility (col. 7, lines 28-39). One of ordinary skill in the art would recognize that to modify the length of the bridge members, the points at which they connect may need to be modified as well. Fischell et al. essentially teach how long and flexible bridge members may be arranged on a stent of similar undulating design as Dang's in order to improve longitudinal flexibility, torsional stability (reduced flaring when bending) and reduced crimping diameter without interfering with eachother (col. 2, lines 37-50; col. 2, lines 58-63; col. 3, lines 17-23; col. 3, lines 31-36; col. 5, lines 10-14; col. 5, lines 2-9). The only steps that the modification requires are moving the location of the bridge members from one lobe to an adjacent outer lobe, repeating this step for each module and altering the length and flexibility of the bridges. Appellant has argued throughout pages 4-6 of the appeal brief that the above modifications would require hindsight analysis in view of Appellant’s invention. Examiner respectfully disagrees and believes that with the suggestions and teachings set forth above, the proposed combination could reasonably result from an analysis of Dang and Fischell et al. alone.

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

/Thomas McEvoy/
Examiner, Art Unit 3731

Conferees:

/Anhtuan T. Nguyen/
Supervisory Patent Examiner, Art Unit 3731

/Thomas C. Barrett/
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